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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/755,004 01/05/01 SHUBER Α EXT-048 **EXAMINER** Г021323 HM12/0910 TESTA, HURWITZ & THIBEAULT, LLP CHUNDURU, S HIGH STREET TOWER ART UNIT PAPER NUMBER 125 HIGH STREET BOSTON MA 02110 1656 DATE MAILED: 09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/755,004	SHUBER, ANTHONY P.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1656	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status			
1) Responsive to communication(s) filed on <u>05 J</u>	anuary 2001 .		
2a) This action is FINAL . 2b) This action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) Claim(s) 1-18 is/are pending in the application.			
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6) Claim(s) is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claims 1-18 are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) The drawing(s) filed on is/are objected to by the Examiner.			
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved.			
12) The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. § 119			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:			
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
Attachment(s)			
15) Notice of References Cited (PTO-892)	18) Interview Summa	ary (PTO-413) Paper No(s)	
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	, <u></u>	al Patent Application (PTO-152)	

U.S. Patent and Trademark Office PTO-326 (Rev. 01-01) Application/Control Number: 09/755,004

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121:

Group I, claims 1-9, 17 and 18 drawn to a method for detecting a helicobacter pylori infection, classified in class 435, subclass 6.

Group II, claims 10-11, drawn to a method for grading a helicobacter pylori infection in a patient classified in class 435, subclass 6.

Group III, claims 12-13, drawn to a method for monitoring progression of a helicobacter pylori infection in a patient, classified in class 435, subclass 6.

Group IV, claims14-15, drawn to a method for evaluating the efficacy of a proposed treatment regimen for a helicobacter pylori infection, classified in class 514, subclass 44.

Group V, claim(s) 16, drawn to a method for diagnosing a gastric disease in a patient, classified in class 435, subclass 6.

- 2. The inventions are distinct, each from the other because of the following:
- (a) The invention in Group I is independent and distinct from each of the inventions in Groups II and III because the method for detecting a helicobacter pylori infection is materially different from a method for grading a helicobacter pylori infection of Group II, is materially different from a method for monitoring progression of a helicobacter pylori infection of Group III. Additionally, the method steps are not needed of Group II or Group III are not needed to practice the invention in Group I. Further, each invention in Groups I-III have different modes of operation, different functions, or different effects.

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- b. The method for evaluating efficacy of treatment regimen for a helicobacter pylori infection of Group IV is independent and distinct from each of Groups V and III because the method for diagnosis of a gastric disease can be used in DNA purification, hybridization assays etc. The method of Group III can be used in gene therapy assays.
- c. The method for grading a helicobacter pylori infection of Group II is independent and distinct from each of Group I and III because the method for detection of Group I can be used in mutation detection etc. and the method for monitoring progression of Group III can be used in gene expression assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search for one group is not required for any other group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru August 27, 2001

W. Gary Jones

Supervisory Patent Examiner Technology Center 1600

7/7/01